

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant	:	Wedel et al.
Appl. No.	:	10/777,838
Filed	:	February 12, 2004
For	:	COMPOSITIONS AND METHODS FOR TREATMENT OF POUCHITIS
Examiner	:	Dana H. Shin
Group Art Unit	:	1635
Confirmation No.	:	5903

**DECLARATION OF INVENTORS UNDER 37 CFR §1.131**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Dear Sir:

We declare and state as follows:

1. We are inventors of the invention claimed in the above-captioned patent application.
2. We are informed that the U.S. Patent and Trademark Office (PTO) has cited a publication entitled "Isis Pharmaceuticals Reports Financial Results and Highlights for the Year 2002," published by PR Newswire, and dated February 11, 2003, as prior art against the above-captioned application. We are informed that the PTO is asserting that the reference "teaches a method of treating ulcerative colitis/pouchitis in a patient comprising administering ISIS 2302."
3. The above-referenced application claims priority to U.S. Provisional Patent Application Serial No. 60/447215, which was filed on February 13, 2003. Example 17 of the 60/447215 application beginning on page 91 is entitled "Treatment of pouchitis with ISIS-2302 with ISIS-2302 enema formulation." This example describes the results of a 6 week study using ISIS 2302 to treat patients with pouchitis. All of the events and activities described in Example 17 were performed in the United States by one or both of us personally, or by others at the direction of one or both of us.

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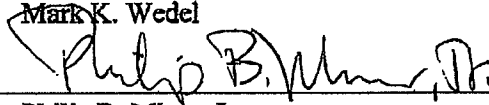
4. This evidence clearly establishes that at least six weeks prior to the filing of the 60/447215 application, we possessed as much of the claimed invention as is allegedly disclosed in the PR Newswire reference. Because the 60/447215 application was filed two days after the date listed on the PR Newswire reference, this evidence establishes that we possessed as much of the claimed invention as is allegedly disclosed in the PR Newswire reference prior to February 11, 2003.

5. We hereby declare that all statements made herein of our own knowledge are true and that all statements made on information or belief are believed to be true, and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful statements may jeopardize the validity of the application or any patent issued thereon.

By: \_\_\_\_\_

Date: \_\_\_\_\_

Mark K. Wedel

By:   
Philip B. Miner, Jr.

Date: 27 Feb 2008

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